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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Richard P. Woychik *et al.*

Serial No.: 09/103,846

Group No.: 1643

Filed: 06/24/98

Examiner:

Entitled: **ALLELIC SERIES OF GENOMIC MODIFICATIONS
IN CELLS**

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STATEMENT TRANSMITTAL**

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Dated: May 24, 1999

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Enclosed please find an Information Disclosure Statement and Form PTO-1449, including copies of the references contained thereon, for filing in the U.S. Patent and Trademark Office.

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Dated: May 24, 1999



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The citations listed below, copies attached, may be material to the examination of the above-identified application, and are therefore submitted in compliance with the duty of disclosure defined in 37 C.F.R. §§ 1.56 and 1.97. The Examiner is requested to make these citations of official record in this application.

The following patents are referred to in the body of the specification:

- U.S. Patent No. 4,683,195 issued July 28, 1987 to Mullis *et al.*;
- U.S. Patent No. 4,683,202 issued July 28, 1987 to Mullis; and
- U.S. Patent No. 4,965,188 issued Oct. 23, 1990 to Mullis *et al.*

The following printed publications are referred to in the body of the specification:

- Russell *et al.* (1979) "Specific-locus test shows ethylnitrosourea to be the most potent mutagen in the mouse," Proc. Natl. Acad. Sci. USA 76:5818-5819;
- Hitotsumachi *et al.* (1985) "Dose-repetition increases the mutagenic effectiveness of *N*-ethyl-*N*-nitrosourea in mouse spermatogonia," Proc. Natl. Acad. Sci. USA 82:6619-6621;

- Shedlovsky *et al.* (1993) "Mouse Models of Human Phenylketonuria," *Genetics* 134:1205-1210;
- Marker *et al.* (1997) "Spectrum of *Bmp5* Mutations From Germline Mutagenesis Experiments in Mice," *Genetics* 145:435-443;
- Zambrowicz *et al.* (1998) "Disruption and sequence identification of 2,000 genes in mouse embryonic stem cells," *Nature* 392:608-611;
- Maniatis *et al.* (1987) "Regulation of Inducible and Tissue-Specific Gene Expression," *Science* 236:1237-1245;
- Voss *et al.* (1986) "The role of enhancers in the regulation of cell-type-specific transcriptional control," *Trends Biochem. Sci.* 11:287-289;
- Dijkema *et al.* (1985) "Cloning and expression of the chromosomal immune interferon gene of the rat," *EMBO J.* 4:761-767;
- Uetsuki *et al.* (1989) "Isolation and Characterization of the Human Chromosomal Gene for Polypeptide Chain Elongation Factor-1 α *," *J. Biol. Chem.* 264:5791-5798;
- Kim *et al.* (1990) "Use of the human elongation factor 1 α promoter as a versatile and efficient expression system," *Gene* 91:217-223;
- Mizushima and Nagata (1990) "pEF-BOS, a powerful mammalian expression vector," *Nuc. Acids. Res.* 18:5322;
- Gorman *et al.* (1982) "The Rous sarcoma virus long terminal repeat is a strong promoter when introduced into a variety of eukaryotic cells by DNA-mediated transfection," *Proc. Natl. Acad. Sci. USA* 79:6777-6781;
- Boshart *et al.* (1985) "A Very Strong Enhancer is Located Upstream of an Immediate Early Gene of Human Cytomegalovirus," *Cell* 41:521-530;
- Kohler *et al.* (1993) "Spectrum of Mutation and Frequency of Allelic Deletion of the p53 Gene in Ovarian Cancer," *J. Natl. Cancer Inst.* 85(18):1513-1519;
- Greenman *et al.* (1998) "Identification of Missense and Truncating Mutations in the *BRCA1* Gene in Sporadic and Familial Breast and Ovarian Cancer," *Genes, Chromosomes & Cancer* 21(3):244-249;
- Zielenski and Tsui (1995) "Cystic Fibrosis: Genotypic and Phenotypic Variations," *Ann. Rev. Genetics* 29:777-807;

- Dean and Santis (1994) "Heterogeneity in the severity of cystic fibrosis and the role of CFTR gene mutations," *Hum. Genet.* 93(4):364-368;
- Sessa *et al.* (1997) "Autosomal dominant polycystic kidney disease: clinical and genetic aspects," *J. Nephrol.* 10(6):295-310;
- Watnick *et al.* (1997) "An unusual pattern of mutation in the duplicated portion of *PKD1* is revealed by use of a novel strategy for mutation detection," *Human Molec. Genetics* 6:1473-1481;
- Veldhuisen *et al.* (1997) "A Spectrum of Mutations in the Second Gene for Autosomal Dominant Polycystic Kidney Disease (PKD2)," *Am. J. Hum. Genet.* 61:547-555;
- Schulte-Merker *et al.* (1992) "The protein product of the zebrafish homologue of the mouse *T* gene is expressed in nuclei of the germ ring and the notochord of the early embryo," *Development* 116:1021-1032;
- Hermann *et al.* (1990) "Cloning of the *T* gene required in mesoderm formation in the mouse," *Nature* 343:617-622;
- Smith *et al.* (1990) "Expression of a Xenopus Homolog of *Brachyury (T)* Is an Immediate-Early Response to Mesoderm Induction," *Cell* 67:79-87;
- Blum *et al.* (1992) "Gastrulation in the Mouse: The Role of the Homeobox Gene *goosecoid*," *Cell* 69:1097-1106;
- Izpisua-Belmonte *et al.* (1993) "The Homeobox Gene *goosecoid* and the Origin of Organizer Cells in the Early Chick Blastoderm," *Cell* 76:645-659;
- Blumberg *et al.* (1991) "Organizer-Specific Homeobox Genes in *Xenopus laevis* Embryos," *Science* 253:194-196;
- Stachel *et al.* (1993) "Lithium perturbation and *goosecoid* expression identify a dorsal specification pathway in the pregastrula zebrafish," *Development* 117:1261-1274;
- Evans *et al.* (1981) "Establishment in culture of pluripotential cells from mouse embryos," *Nature* 292:154-156;
- Martin (1981) "Isolation of a pluripotent cell line from early mouse embryos cultured in medium conditioned by teratocarcinoma stem cells," *Proc. Natl. Acad. Sci. USA* 78:7634-7638;

- Magnuson *et al.* (1982) "The development of monosomy 19 mouse embryos," *J. Embryo. Exp. Morph.* 69:223-236;
- Doetschman *et al.* (1988) "Establishment of Hamster Blastocyst-Derived Embryonic Stem (ES) Cells," *Dev. Biol.* 127:224-227;
- Tokunaga *et al.* (1989) "Establishment of the Mouse Embryonic Stem Cell Lines from Whole Blastocysts and Isolated Inner Cell Masses," *Jpn. J. Anim. Reprod.* 35:173-178;
- Eistetter (1989) "Pluipotent Embryonal Stem Cell Lines Can Be Established from Disaggregated Mouse Morulae," *Dev. Gro. Differ.* 31:275-282;
- Matsui *et al.* (1992) "Derivation of Pluripotential Embryonic Stem Cells from Murine Primordial Germ Cells in Culture," *Cell* 70:841-847;
- Resnick *et al.* (1992) "Long-term proliferation of mouse primordial germ cells in culture," *Nature* 359:550-551;
- Doetschman *et al.* (1985) "The *in vitro* development of blastocyst-derived embryonic stem cell lines: formation of visceral yolk sac, blood islands and myocardium," *J. Embryol. Exp. Morphol.* 87:27-45;
- Lallemand *et al.* (1990) "An *in situ* assessment of the routes and extents of colonisation of the mouse embryo by embryonic stem cells and their descendants," *Development* 110:1241-1248;
- Bradley *et al.* (1984) "Formation of germ-line chimaeras from embryo-derived teratocarcinoma cell lines," *Nature* 309:255-256;
- Gossler *et al.* (1986) "Transgenesis by means of blastocyst-derived embryonic stem cell lines," *Proc. Natl. Acad. Sci. USA* 83:9065-9069;
- Robertson *et al.* (1986) "Germ-line transmission of genes introduced into cultured pluripotential cells by retroviral vector," *Nature* 323:445-448;
- Beddington *et al.* (1989) "An assessment of the developmental potential of embryonic stem cells in the midgestation mouse embryo," *Development* 105:733-737;
- Suemori *et al.* (1990) "A mouse embryonic stem cell line showing pluripotency of differentiation in early embryos and ubiquitous β -galactosidase expression," *Cell Differ. Dev.* 29:181-186;

- Strojek *et al.* (1990) "A Method for Cultivating Morphologically Undifferentiated Embryonic Stem Cells from Porcine Blastocysts," *Theriogenology* 33:901-914;
- Piedrahita *et al.* (1990) "On the Isolation of Embryonic Stem Cells: Comparative Behavior of Murine, Porcine and Ovine Embros," *Theriogenology* 34:879-901;
- Notarianni *et al.* (1991) "Derivation of pluripotent, embryonic cell lines from the pig and sheep," *J. Reprod. Fert. (Suppl.)* 43:255-260;
- Saito *et al.* (1992) "Bovine embryonic stem cell-like cell lines cultured over several passages," *Roux's Arch. Dev. Biol.* 201:134-141;
- Stice *et al.* (1996) "Pluripotent Bovine Embryonic Cell Lines Direct Embryonic Development Following Nuclear Transfer," *Biol. Reprod.* 54:100-110;
- Sukoyan *et al.* (1992) "Isolation and Cultivation of Blastocyst-Derived Stem Cell Lines from American Mink (*Mustela vison*)" *Mol. Reprod. Dev.* 33:418-431;
- Brenin *et al.* (1997) "Rat Embryonic Stem Cells: A Progress Report" *Transplant Proc.* 29:1761-1765;
- Iannaccone *et al.* (1994) "Pluripotent Embryonic Stem Cells from the Rat Are Capable of Producing Chimeras," *Dev. Biol.* 163:288-292;
- Sun *et al.* (1995) "ES-like cell cultures derived from early zebrafish embryos," *Mol. Mar. Biol. Biotechnol.* 4:193-199;
- Evans (1989) "Potential for Genetic Manipulation of Mammals," *Mol. Bio. Med.* 6:557-565;
- Johnson *et al.* (1989) "Genetic Correction of Hereditary Disease," *Fetal Ther.* 4 (Suppl.) 1:28-39;
- Babinet *et al.* (1989) "Transgenic Mice," *Genome* 31:938-949;
- Russell *et al.* (1990) "Factors affecting the nature of induced mutations," in *Biology of Mammalian Germ Cell Mutagenesis*, Banbury Report 34, Cold Spring Harbor Laboratory Press, pp. 271-289;
- Rinchik (1991) "Chemical mutagenesis and fine-structure functional analysis of the mouse genome," *Trends in Genetics* 7(1):15-21;

- Sehlmeyer and Wobus (1994) "Lower mutation frequencies are induced by ENU in undifferentiated embryonic cells than in differentiated cells of the mouse in vitro," *Mutation Research* 324:69-76;
- Shibuya and Morimoto (1993) "A review of the genotoxicity of 1-ethyl-1-nitrosourea," *Mutation Res.* 297:3-38;
- Justice *et al.* (1988) "Three ENU-induced alleles of the murine quaking locus are recessive embryonic lethal mutations," *Genet. Res.* 51:95-102;
- Vitaterna *et al.* (1994) "Mutagenesis and Mapping of a Mouse Gene, *Clock*, Essential for Circadian Behavior," *Science* 264:719-725;
- Hammer *et al.* (1986) "Genetic Engineering of Mammalian Embryos," *J. Animal Sci.*:63:269-278;
- Hammer *et al.* (1985) "Production of transgenic rabbits, sheep and pigs by microinjection," *Nature* 315:680-683;
- Bradley *et al.* (1987) in *Teratocarcinomas and Embryonic Stem Cells: A Practical Approach*, Ed. Robertson E.J. (IRL, Oxford, U.K.), pp. 113-151;
- Nagy *et al.* (1990) "Embryonic stem cells alone are able to support fetal development in the mouse," *Development* 110:815-821;
- Miki *et al.* (1994) "A Strong Candidate for the Breast and Ovarian Cancer Susceptibility Gene *BRCA1*," *Science* 266:66-71; and
- Friedman *et al.* (1994) "Confirmation of *BRCA1* by analysis of germline mutations linked to breast and ovarian cancer in ten families," *Nat. Genet.* 8:399-404.

This Information Disclosure Statement under 37 C.F.R. §§ 1.56 and 1.97 is not to be construed as a representation that a search has been made, that additional information material to the examination of this application does not exist, or that any one or more of these citations constitutes prior art.

Dated: 24 May 1999


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